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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/162,597	09/29/98	BANDMAN O	PF-0126-1DRI

EXAMINER
JOHNSON, N

ART UNIT	PAPER NUMBER
1642	7

HM22/0331

LEGAL DEPARTMENT
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DATE MAILED: 03/31/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days,~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 13, 20-24 is/are pending in the application.
Of the above, claim(s) 21-24 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are withdrawn from consideration.
☒ Claim(s) 13, 20 is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

PTOL-326 (Rev. 9/96)

★ U.S. GPO: 1996-421-632/40206

1. Claims 1-12, 14-19 have been canceled.

Claims 13 and 20-24 are pending.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 13 and 20, drawn to a protein and pharmaceutical compositions of said protein, classified in classes 530 and 514, subclasses 350 and 2, respectively.

II. Claims 21-23, drawn to antibodies, classified in class 530, subclass 387.9. Claims 22-23 will be examined with Group ~~II~~ III to the extent that they read on antibodies.

III. Claims 22-23, drawn to antagonists, classified in class 530, subclass 300.

IV. Claim 24, drawn to a method of treating cancer with an antagonist, classified in class 514, subclass 2.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-III are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The products of Groups II and III and the method of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist of Group III (for example, an antibody of Group II) can be used in *in vitro* diagnostic assays.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Leanne Price on March 25, 1999 a provisional election was made with traverse to prosecute the invention of Group I, claims 13 and 20. Affirmation of this election must be made by applicant in responding to this Office action. Claims 21-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

7. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "having" is vague and indefinite. It is unclear if the recitation is to be interpreted as open language ("comprising") or closed language ("consisting of").

8. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "compositions comprising the protein having the amino acid sequence of SEQ ID NO:3 in conjunction with a suitable pharmaceutical carrier," does not reasonably provide enablement for claims broadly drawn to "**pharmaceutical** compositions comprising the protein having the amino acid sequence of SEQ ID NO:3 in conjunction with a suitable pharmaceutical carrier." The claim limitation "Pharmaceutical composition" is broadly interpreted to read on a composition effective in the *in vivo* treatment of humans. The identification of such compositions, for *in vivo* human therapy, is highly experimental and unpredictable. The specifications has identified no biological activity whatsoever of the protein comprising the amino acid sequence of SEQ ID NO:3 and does not exemplify the use of said protein as a therapeutic. Absent such information, it is highly unpredictable that such a composition would have effectiveness as an in

vivo therapeutic and one skilled in the art would not be able to practice the claimed invention without undue experimentation. Thus, due the unpredictability of therapeutics in general and in absence of any guidance and/or working examples concerning the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 13 is rejected under 35 U.S.C. 102(a) as being anticipated by Lehninger (1974 Biochemistry textbook, p. 962). Tables 34-1 and 34-3 disclose single amino acid residues that are the same as the claimed "fragments thereof" of the "protein comprising the amino acid sequence of SEQ ID NO:3."

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy A. Johnson, Ph.D. whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday-Friday from 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax number for the group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nancy A Johnson
Primary Examiner

March 29, 1999